

To: Naomi Kulakow@OFL@FDA.CFSAN
From: "Phil Howry" <phil@texas.net>
Certify: N
Priority: Normal
Subject: Public Meeting (CFSAN)
Date: Tue May 25 14:40:27 1999
Attached: attach1

99-1174

Dear Ms. Kulakow,

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As the victim of dietary supplements containing ephedrine (4/28/94 death of wife), the FDA's continuing efforts to control the sale and distribution of dietary supplements containing Ma Huang (ephedrine) or, any man-made ephedrine, is of extreme importance to me.

Last week, the Texas Department Health's (TDH) Regulatory Board recommended to the full board a very weak labeling procedure for dietary products sold in Texas. Based on the empirical data of adverse effects reported in Texas and the results of at least two (2) multi-plaintiff lawsuits, the TDH was set to follow other states in regulating these products by listing them as "prescription only". The Texas Medical Association recommended such action and officially recorded this position in the testimony of Dr. Nicholas Curry before the board. However, the Dietary Supplement Industry's \$2 million lobby effort in Texas was just too much to overcome. The board, with the exception of one member, was sufficiently convinced by the Commissioner Health Dr. Reyn Archer's warnings of industry lawsuits if the rules were not passed, voted with the industry's "milk toast" warning label. Of note, the lone no vote came from the licensed doctor member, Mario R. Anzadula, M.D. Also of note, the Commissioner of Health is not licensed in Texas. I testified both days against the sale and distribution of ephedrine products.

Having personally experienced a four (4) year long legal battle with this industry I became aware of how unregulated and out-of-control this multi-level marketing scheme truly is and that their total focus is not on the safety or efficacy of this product but, on its income potential.

Ephedrine related injuries continue to be reported in Texas and across the nation. Dr. David Samenuk of New England Medical Center in Boston and Dr. George Blackburn Associate Professor of Nutrition at Harvard Medical School and dietary supplements expert agrees "You can die from taking this product" (Metabolife). The industry can produce no peer reviewed studies, conclusive safety study or any legitimate testing to support their products claims or of its safety. Ephedrine products must be banned or at least restricted to prescription only.

I have an interest in speaking before the committee on June 8th in Washington, D.C. Please advise me of the process to do this.

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